

## REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

### **I. Status of the Claims**

Claim 73 was cancelled previously. Claims 1, 26 and 50 have been amended to recite that “the surface stabilizer is essentially free of intermolecular cross-linkages”, with support in the original specification, for example, at page 14, paragraph [0046]. Applicants acknowledge the finality of this Office Action. Nevertheless, because the amendments to the claims: (i) do not introduce any new matter, (ii) do not require additional search, and (iii) place the application in condition for allowance or at least in better condition for appeal, Applicants respectfully request entry of this amendment. Upon entry, claims 1-72 will be pending.

### **II. Rejection of Claims under 35 U.S.C. §102(b)**

Claims 1, 3-6, 9, 10, 12, 14-17, 26-29, 32-35, 38, 39, 41, 50, 52-55, 58, 59, 61 and 63-67 are rejected under 35 U.S.C. §102(b) for alleged anticipation by U.S. Patent No. 6,184,220 to Turck et al. (“Turck”). Applicants respectfully traverse the rejection.

#### **A. Turck fails to teach a surface stabilizer adsorbed to the surface of the meloxicam particles.**

As submitted in the prior response, Turck teaches meloxicam that is adsorbed exclusively onto and between the SiO<sub>2</sub> strands, where SiO<sub>2</sub> forms a 3-D solid structure. This teaching is clearly distinguishable from the claimed invention, where the surface stabilizer is adsorbed on the surface of the active agent particles.

The Examiner asserts that a surface stabilizer adsorbed on the surface of the active agent particles is an “inherent” property “because Turck teaches the same process required [*sic*] by the present invention” (final Office Action, page 7, lines 1-4). Applicants respectfully disagree.

First, in support of the obviousness rejection, the Examiner states: “Turck does not teach the claimed surface stabilizer” (final Office Action, page 3, lines 9-10). However, the examiner continues to assert that for purposes of this anticipatory rejection, Turck does teach a surface stabilizer, that is SiO<sub>2</sub>, and that this surface stabilizer is adsorbed on the surface of meloxicam. In addition to the examiner’s own contradictory statements, Turck’s own express teaching contravenes the Examiner’s interpretation of Turck. Turck clearly states that SiO<sub>2</sub> (i.e., the “surface stabilizer” of Turck) forms a 3-D structure with meloxicam trapped between the SiO<sub>2</sub> strands. See abstract, and column 3, lines 45-65. In support of the rejection, the Examiner is asking one of ordinary skill in the art to infer that when Turck states that the meloxicam is trapped within the 3-D matrix of SiO<sub>2</sub>, Turck actually meant that the SiO<sub>2</sub> is adsorbed on the surface of the meloxicam. Such an inference is unsupported.

Second, the claims have been amended to read that “wherein the surface stabilizer is essentially free of intermolecular cross-linkage.” Assuming *arguendo* that the SiO<sub>2</sub> is a surface stabilizer as defined by the Applicant Turck describes that the SiO<sub>2</sub> forms a cross-linked structure. See Turck, column 3, line 54. A cross-linked structure is not essentially free of intermolecular cross-linkages. Therefore, Turck’s composition is clearly distinguishable from the claimed composition.

Finally, inherency is established when two products are identical, but the product of the prior art does not recite a property of the claimed invention. Inherency is not established when the processes of making two products are identical. MPEP 2112 sets forth that anticipation by inherency may be established “once a reference teaching a product appearing to be substantially identical [to the claimed product].” In this instance, the process of making the claimed composition entails contacting meloxicam with at least one surface stabilizer and co-grinding the

surface stabilizer and the meloxicam. In principle, this process could be applied to any ingredients, but there is no guarantee that the end product will comprise a surface stabilizer adsorbed on the surface of any substance used in this process, as required by the claimed invention.

**B. Turck fails to teach an effective average particle size of less than about 2000 nm.**

The Examiner asserts that Turck anticipates the claimed invention because Turck teaches that at least 50% of the particles are smaller than 10  $\mu\text{m}$ , and that “smaller than 10  $\mu\text{m}$  includes 2  $\mu\text{m}$  or 2000 nm” (final Office Action, page 7, line 18).

Although the prior-art particle size range of less than 10  $\mu\text{m}$  overlaps the claimed particle size range of less than about 2000 nm, pursuant to MPEP 2131.03 the prior-art broader range only anticipates the claimed narrower range if the prior art discloses the claimed range “with sufficient specificity.” In this case, the only working example in the cited art does not disclose Applicants’ claimed particle size. Therefore, the cited art fails to disclose the claimed particle size range with sufficient specificity to anticipate the claimed invention.

Furthermore, a declaration was previously submitted by Applicants to demonstrate the superior  $T_{\text{max}}$  achieved by the claimed composition. Accordingly, the claimed particle size range is non-obvious over the prior art particle size range.

**C. Claimed composition exhibits superior  $T_{\text{max}}$  to that of a non-nanoparticulate meloxicam formulation or that of Turck’s composition.**

The Examiner contends that “Turck teaches a nanoparticulate meloxicam formulation that exhibits a shorter time to  $T_{\text{max}}$  when compared to the time to  $T_{\text{max}}$  of the non-nanoparticulate meloxicam formulation” (final Office Action, page 9, lines 5-7), thereby meeting the claim limitation “wherein in comparative pharmacokinetic testing with a non-nanoparticulate formulation of meloxicam having the same dosage strength and form, the composition exhibits a

shorter time to  $T_{\max}$  when compared to the time to  $T_{\max}$  of the non-nanoparticulate meloxicam formulation.”

To this end, the Examiner contends that the claimed properties, such as  $T_{\max}$ , are “inherent” (final Office Action, page 3, first paragraph), considering the logic that the same compositions would have exhibited the same  $T_{\max}$ . Given that, then different compositions would exhibit different  $T_{\max}$ . Applying this logic, if Turk’s composition were in the nanometer size range like the claimed invention, and the Examiner assumptions are true that the  $T_{\max}$  is inherent, then one of ordinary skill in the art would expect Turk to report a  $T_{\max}$  which is the same as the claimed composition. To the contrary, Turk reported a  $T_{\max}$  of 2 hr (1.5-5 hr) (Col. 10, lines 1 and 2) were as Applicant’s Declaration reported a  $T_{\max}$  of 0.667 hrs. Therefore, one skilled in the art would not have concluded that Turk’s composition has the same particle size as the Applicant’s claimed invention. Thus Turk does not anticipate the claimed composition. .

In view of the foregoing, withdrawal of the rejection under 35 U.S.C. §102(b) is warranted.

### **III. Rejection of Claims under 35 U.S.C. §103(a)**

#### **A. Turck and Liversidge**

Claims 1-17, 26-42 and 50-67 are rejected under 35 U.S.C. §103(a) for alleged obviousness over Turck and PCT Publication No. WO 93/25190 by Liversidge et al. (“Liversidge”). Applicants respectfully traverse the rejection.

The motivation to combine the teachings of the cited references is lacking. The Examiner acknowledges that “Turck does not teach the claimed surface stabilizer” (final Office Action, page 3, lines 9-10), but asserts that “it would have been obvious to one of ordinary skill in the art

to modify the process for preparing the active particle of Turck to include other surface stabilizer in view of the teachings of Liversidge to obtain the claimed invention” (id, page 4, lines 3-6).

Turck and Liversidge teach away from each other in terms of the surface stabilizers. As discussed above, Turck requires that the surface stabilizer form a cross-linked 3-D structure. In contrast, Liversidge explicitly teaches that the surface stabilizer is “essentially free of intermolecular crosslinkages” (Liversidge, page 6, lines 29-31). Therefore, contrary to the Examiner’s contention, one skilled in the art would not have been motivated to combine the teachings of the cited references to include Liversidge’s surface stabilizers.

A person of ordinary skill in the art would also have no reason to use the surface stabilizers of Liversidge in Turck. The SiO<sub>2</sub> of Turck would have to be completely removed from the composition and replaced by the surface stabilizers of Liversidge. There is no teaching, express or inherent, to provide a reason for one of ordinary skill in the art to do so.

**B. Turck, Desai and Courteille**

Claims 18-25, 43-49 and 68-72 are rejected under 35 U.S.C. §103(a) as being allegedly obvious over Turck in view of PCT Publication No. WO 01/45706 by Desai et al. (“Desai”) or U.S. Patent No. 5,384,124 to Courteille et al. (“Courteille”). Applicants respectfully traverse the rejection.

According to the Examiner, Desai and Courteille are cited for the alleged teaching of a second particle population. As discussed above, the cited art fails to teach or suggest each and every element of the claimed invention. Because the claims at issue depend from non-obvious base claims, they are non-obvious as well.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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